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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,937	08/08/2006	Michael Ausborn	33566-US-PCT	1841
1095 7590 10/21/2010				
NOVARTIS				
CORPORATE INTELLECTUAL PROPERTY				
ONE HEALTH PLAZA 101/2				
EAST HANOVER, NJ 07936-1080				
EXAMINER				
PACKARD, BENJAMIN J				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
10/21/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/581,937

Applicant(s)

AUSBORN ET AL.

Examiner

Benjamin Packard

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,14-16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) 15,16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed 8/18/10, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 6, and 7 stand rejected under 35 U.S.C. 102(a) as being anticipated by Dadsetan et al (Journal of Controlled release, 93 (2003) pp 259-270).

Applicants assert Dadsetan et al only teaches insertion of a film into a wire mesh cage, but is silent as to surface coating with a biodegradable polymer.

Examiner disagrees. Contrary to Applicants assertion, Examiner interprets a polymer film which is placed within a wire mesh provides a "surface coating", given the interior of the mesh would be lined with the film. As such, the film would provide a "coating" of the interior surface, where coating Whether the coating is sprayed on or laid on, the end result is the same, i.e. a wire mesh with an interior lined with the instantly claimed polymer. Further, the instant specification does not define the term "coating", but does provide some direction as to the breadth of its interpretation where at pg 17, lines 15-24, various methods of applying the polymer are disclosed, including

dip-coating, brush-coating, and printing. The end result would be a film polymerized on the device, which appears to be the same result disclosed in the prior art.

Claims 1, 3-5, and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Acemoglu et al (WO 1995/006077).

Applicants assert the multiple uses of the term "device" in reference to stents and the polymer layer to require separate layers. Additionally, Applicants assert the Office Action does not provide any teaching by Acemogly of a biodegradable polymer coating "upon", as opposed to "within", a device.

Examiner disagrees. As now amendment, the instant claims are still anticipated, given the rhIL-6 may be construed as the devices which are then coated with the biodegradable polymer.

As noted in the rejection dated 3/15/10 and incorporated herein by reference, there is no limiting definition of "device", therefore it may be interpreted reasonably broadly to include devices comprising particles of active agent which are to be administered to patients for their known functionality.

Claim Rejections - 35 USC § 103

Claims 1, 3-7, and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dadsetan et al (Journal of Controlled release, 93 (2003) pp 259-270) in view of Acemoglu et al (WO 1995/006077).

Applicants assert Dadsetan et al does not disclose coating a stent, but instead insertion of PEC into the stent, therefore a *prima facie* case of obviousness has not been made for the amended claims.

Examiner disagrees. As discussed above, Dadsetan et al does disclose a coated device, therefore a *prima facie* case of obvious is met.

Claims 1, 3-7, and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda (US Pregrant Pub 2001/0007083).

Applicants assert the instant rejection is improper where the Office Action does not address the Graham factual inquiries as required but instead provides conclusions without articulated reasoning. Further, Applicants assert that the mere fact that the prior art may be modified does not make that modification obvious unless the prior art suggests the desirability thereof.

Examiner disagrees. The Graham factual inquiry, while not specifically enumerated, was discussed in the rejection where the prior art was discussed, the differences were laid out, and the motivation was to modify the stent was disclosed. To reiterate, Roorda was cited for the teaching that it was known to apply biodegradable coatings to stents with active agents contained therein (§§ 32 and 47). Such teaching provides motivation to coat a stent with a drug laden biodegradable coating. The skilled artisan, when reading this, would look to the additional disclosure of Roorda in order to determine what biodegradable coatings may be used. Hence, Examiner cited § 34 which discloses representative examples of biodegradable polymeric materials.

Applicants' assertion that such a list does not provide motivation to select a specific species is not well founded. Where the prior art specifically lists the various species within a genus suggests disclosed to be representative examples, it would reasonably be expected that the skilled artisan may select any of the species from the genus with a reasonable expectation of success that the resulting coated stent of any of the polymers would produce a coated stent with the desired properties.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612